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Introduction

Transplantation is the procedure involving the removal of a bodily organ or tissue from one person, and the insertion of that organ or tissue into another person to replace a damaged organ or tissue.

Definition of Terms:
Allograft – transplant from one individual to another (synonymous with homograft)
Heterotopic graft – transplant placed in a site different than the organ's normal location
Orthotopic graft – transplant placed in its normal anatomical site
Syngeneic graft (isograft) – transplant between identical twins
Xenograft – transplant between different species

Organ transplantation is now well established as an effective treatment for selected patients with end-stage organ failure. Transplantation of the kidney, liver, pancreas, heart, and lungs are all routine procedures, and transplantation of the small intestine is becoming more widely practiced. Currently, transplant activity is limited only by the shortage of cadaveric organs.

The following policy contains the minimal criteria for solid organ transplants. Additional justification may be required at the discretion of the Division of Medical Assistance Hospital Consultant staff.

1.0 Description of the Procedure

Kidney transplant is a procedure to implant a healthy kidney into a patient with a diseased or failing kidney. The donor kidney may come from a living donor or recently deceased donor.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid eligible individuals with a need for this specialized treatment confirmed by a licensed physician are eligible as long as they meet individual eligibility requirements. Medicaid recipients may have service restrictions due to their eligibility category, which would make them ineligible for this service.

2.2 Special Provisions

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that provides recipients under the age of 21 with medically necessary health care to correct or ameliorate a defect, physical or mental illness or a condition identified through a screening examination. While there is no requirement that the service, product or procedure be included in the State Medicaid Plan, it must be listed in the federal law at 42 U.S.C. § 1396d(a). Service limitations on scope, amount or frequency described in this coverage policy do not apply if the product, service or procedure is medically necessary.

The Division of Medical Assistance's policy instructions pertaining to EPSDT are available online at http://www.dhhs.state.nc.us/dma/prov.htm.

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3.0 When the Procedure is Covered

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for coverage.

3.1 Coverage Criteria

The N.C. Medicaid program covers kidney transplants for patients who meet indications for transplantation related to the following disease process after their creatinine clearance is calculated using the Cockcroft-Gault formula for adults and the Schwartz and Counahan-Barratt Methods calculator for children and adolescents up to 18 years of age. The GFR must be 30ml/min for cadaveric/deceased donor requests and 20ml/min for living donor requests (this list is not all inclusive):

1. obstructive uropathy
2. hemolytic uremic syndrome
3. acute tubular necrosis
4. hypertensive nephrosclerosis
5. systemic lupus erythhematosus
6. polyarteritis
7. Wegener's granulomatosis
8. cortical necrosis
9. renal artery/vein occlusion
10. chronic pyelonephritis
11. Henoch-Schonlein purpura
12. IGA nephropathy
13. diabetes
14. polycystic kidney disease
15. anti-glomerular base membrane disease
16. focal glomerulosclerosis
17. analgesic nephropathy
18. heavy metal poisoning
19. nephritis
20. amyloid disease
21. Fabry's disease
22. Cystinosis
23. oxalosis
24. horseshoe kidney
25. Wilms tumor
26. myeloma
27. renal aplasia/hypoplasia
28. renal-cell carcinoma
29. trauma requiring nephrectomy
30. sickle cell disease
31. scleroderma
32. urolithiasis
33. tuberous sclerosis
34. membranoproliferative glomerulonephritis
35. membranous glomerulonephritis
36. chronic glomerulonephritis

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3.2 Donors

3.2.1 Cadaveric/Deceased Organ Donations

Donor expenses **(procuring, harvesting, and associated surgical and laboratory costs)** for cadaveric/deceased organ donations are covered for a kidney transplant if the transplant recipient has received prior approval for a cadaveric/deceased organ transplant procedure.

3.2.2 Living Organ Donations

Donor expenses **(procuring, harvesting, and associated surgical and laboratory costs)** for living organ donations are covered for a kidney transplant if the transplant recipient has received prior approval for a living organ transplant procedure.

Medicaid only covers reimbursement for the approved donor. Medicaid does not cover expenses for donors who are tested and not approved as the donor.

Refer to **Attachment A** for billing guidance on donor related costs.

4.0 When the Procedure is Not Covered

Kidney transplants are not covered when the medical necessity criteria listed in **Section 3.0** are not met. Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for non-coverage.

The N.C. Medicaid program does not cover kidney transplants when one of the following conditions exists (not all inclusive):

4.1 Absolute

1. HIV positive
2. active malignancy
3. untreated or irreversible end-stage illness
4. active vasculitis
5. active infection
6. alcohol abuse within last 12 months
7. history of or active substance abuse – must have documentation of substance abuse program completion plus six months of negative sequential random drug screens

   Note: To satisfy the requirement for sequential testing as designated in this policy, the Division of Medical Assistance (DMA) must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.
8. current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable
9. psychosocial history that would limit ability to comply with medical care pre and post transplant

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4.2 Relative

1. age more than 70 years
2. cardiovascular disease and risk (EF < 40%)
3. chronic liver disease (chronic hepatitis B or C)
4. progressive pulmonary disease

4.3 Living Donor

Absolute contraindications to organ donation include a donor who has:

1. a transmissible infectious disease that will adversely affect the recipient such as HIV, active hepatitis B virus (HBV) infection, West Nile virus, encephalitis of unknown cause, Jakob-Creutzfeldt's disease, malaria or disseminated tuberculosis
2. active visceral or hematologic neoplasm
3. clinical signs that indicate the organ is unlikely to function

5.0 Requirements for and Limitations on Coverage

All applicable N.C. Medicaid policies and procedures must be followed in addition to the ones listed in this policy.

All procedures must be prior approved by DMA.

6.0 Providers Eligible to Bill the for Procedure

Physicians enrolled in the N.C. Medicaid program who perform this procedure may bill for this service.

7.0 Additional Requirements

FDA approved procedures, products, and devices for implantation must be utilized.

Implants, products, and devices must be used in accordance with all FDA requirements current at the time of surgery.

A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the recipient's medical record and made available for review upon request.

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8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 1987

Revision Information:

Date	Section Revised	Change
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.
	Section 3.1	The coverage criteria was revised to indicate that the creatinine clearance rate of 30ml/min is applicable to patients with cadaveric/deceased donor requests and a creatinine rate of 20ml/min is applicable to patients with living donor requests. The creatinine clearance calculation method was revised to indicate that the Cockcroft-Gault formula is used for adults and the Schwartz and Counahan-Barratt Methods GFR method is used for children and adolescents up to 18 years of age. Items 34, 35, and 36 were added as criteria for coverage.
	Section 3.2	The stipulation that living donor donations are only covered when the donor is a Medicaid recipient was deleted.
	Section 3.2.1	This section was reformatted to address cadaveric/deceased organ donations
	Section 3.2.2	This section was added to address living organ donations.
	Section 4.3	This section was added to address contraindications for living organ donations.
	Attachment A	Billing instructions for living organ donations and cadaveric/deceased organ donations were added.

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Attachment A
Claims Related Information

Reimbursement requires compliance with all Medicaid guidelines including obtaining appropriate referrals for recipients enrolled in the Medicaid Managed Care programs.

A. Claim Type

1. Physicians bill professional services on the CMS-1500 claim form..
2. Hospitals bill for services on the UB-92 claim form.

B. Diagnosis Codes that Support Medical Necessity

Providers must bill the ICD-9-CM diagnosis code to the highest level of specificity that supports medical necessity.

C. Procedure Codes

1. CPT Procedures Codes

50300	50320	50340	50360	50365	50380

2. RC Codes

Code	**Description**
811	Living organ donation
812	Cadaveric/deceased organ donation

D. Providers must bill their usual and customary charges.

E. Billing for Donor Expenses

Donor expenses for non-Medicaid donors are billed on the Medicaid recipient's transplant claim using the recipient's Medicaid identification number. Donor expenses for Medicaid donors are billed on the Medicaid donor's claim using the donor's Medicaid identification number.

In all cases, physician professional fees are billed on the CMS-1500 or 837 professional claim transaction and the facility charges are billed on the UB-92 or 837 institutional claim transaction using the appropriate Revenue Code.